DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

October 24, 2001

Bret Gersel
Supervisor
Open MRI of Inland Valley
36243 Inland Valley Drive; Suite #20
Wildomar, CA 92595-9547

W/L Number: 10 - 02
Inspection ID: 2242550001
CFN: 20-32,460
FEI: 3003459565

Dear Mr. Gersel:

We are writing to you because on October 4, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Phantom quality control (QC) records were missing for the weeks of December 8th and December 15th of the year 2000 plus the weeks of February 12th, February 28th, March 30th, July 6th, and August 22nd of the year 2001 for unit #1 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in the mammography room. Patient mammograms were performed during the aforementioned time periods.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.

- Level 2: Corrective action before further exams (for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits) was not documented for unit #1 (a [redacted] machine, model [redacted], serial number [redacted], which is located in the mammography room.

- Level 2: Failed to produce documents verifying that the interpreting physician, [redacted], met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.

- Level 2: Failed to produce documents verifying that the interpreting physician, [redacted] met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.

- Level 2: Failed to produce documents verifying that the interpreting physician, [redacted], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.

- Level 2: Failed to produce documents verifying that the interpreting physician, [redacted], met the initial requirement of having forty (40) hours of medical education in mammography prior to April 28, 1999.

- Level 2: In January 2001, mammograms were processed in processor #1 (a [redacted] machine, model [redacted], which is located in the darkroom, when it was out of limits on at least two (2) but less than five (5) days.

- Level 2: Failed to produce documents verifying that the interpreting physician, [redacted], met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U. S. Food and Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
(949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food and Drug Administration, P.O. Box #6057, Columbia, MD 21045-6057 (telephone: 1-800-838-7715) or through the Internet at http://www.fda.gov

If you have more specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Scott Goff (Compliance Officer) at telephone number 949-798-7644 who is assigned this case.

Sincerely,

Alonza E. Cruse
District Director

cc:

State of California
Dept. of Health Services
Radiological Health Unit; Region #5
1800 East Lambert; Suite #125
Brea, CA 92821-4370